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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,144

09/09/2003

David Alexander

IMMR-IMD0002E

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05/17/2007

IMMERSION -THELEN REID BROWN RAYSMAN & STEINER LLP

P.O. BOX 640640

SAN JOSE, CA 95164-0640

EXAMINER

EPSHTEYN, ALEXANDER

ART UNIT

PAPER NUMBER

3714

MAIL DATE

DELIVERY MODE

05/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/657,144

Applicant(s)

ALEXANDER ET AL.

Examiner

Alex Epshteyn

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3714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 2140 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17,24-28 and 32-38 is/are allowed.
- 6) ☒ Claim(s) 21-23,29-31, 39-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 102 as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/923,477, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for all the claims of this application. The prior filed application bears no mention of, among other features, the retainer and ring configuration or of a pivotable mock anatomical site. As such, the application has been given a date of 28 January 1998 commensurate with the filing of the instant application. In the response, Applicant recites that the 08/923/477 application provides adequate support for the above mentioned feature. However, Applicant fails to cite exactly where such support is specified and as such, the objection to the priority claim stands.

Claim Rejections - 35 USC § 112

The rejections of claims 17 and 28-29 under 35 USC 112 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US Patent No. 5,828,197) in view of Lang et al. (US Patent No. 5,480,307).

Regarding claim 21, Martin discloses a method comprising inserting a peripheral device into a guide tube (col. 15, lines 14-16), the guide tube being disposed within a resilient material (col. 15, lines 20-21), the resilient material being configured to simulate feedback forces as the peripheral device is received in the guide tube (col. 15, lines 29-30, 42-45). Martin further discloses a mock anatomical site with an orifice (Figure 5). Martin also discloses passing the peripheral device through a first retainer, which is substantially fixed to a first ring and guiding the peripheral device through a second retainer, which is substantially affixed to a second ring. (15: 9-16). The first retainer is the nasal passage and the second passage is the simulated sinus cavity which are both attached to rings of mechanism 32. Martin does not expressly disclose that the mock

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anatomical site can be pivoted to a desired position relative to a housing or that it can be locked in a desired position using a locking assembly coupled to the pivoting mechanism. However, Lang discloses a similar mock anatomical site for simulations, where the mock anatomical site can be pivoted by the user to a desired position, and can subsequently be locked in that position (col. 7, line 65 – col. 8, line 6). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Lang into the method of Martin in order to allow the user flexibility in setting up the apparatus correctly for any given procedure, and in order to allow for a more realistic simulation of the actual procedure.

Regarding claim 22, the method steps of claim 21 are intended to simulate a medical procedure using the mock anatomical site as a point of entry into a simulated body (Abstracts of both references).

Regarding claims 23 and 30, both Lang and Martin teach that the mock anatomical site is a mock face (Figure 5 of Martin, Figure 1 of Lang). Furthermore, regarding claim 23, Lang teaches that the pivoting includes pivoting the face to a position simulating an individual lying down (Figure 10).

Regarding claim 29 and 31, Martin discloses a apparatus including a housing (fig. 5a), a resilient material being configured to simulate feedback forces as a peripheral device is received in the guide tube proximate to the orifice and the housing (col. 15, lines 29-30, 42-45). Martin further discloses a mock anatomical site with an orifice (Figure 5). Martin further discloses a hollow member extending through the resiliency-providing material and between the orifice and the housing, the hollow

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member being configured to guide a peripheral device from the orifice into the housing and wherein the mock anatomical site is coupled to the housing (15: 9-16). Martin does not expressly disclose that the mock anatomical site can be pivoted to a desired position relative to a housing or that it can be locked in a desired position using a locking assembly coupled to the pivoting mechanism. However, Lang discloses a similar mock anatomical site for simulations, where the mock anatomical site can be pivoted by the user to a desired position, and can subsequently be locked in that position (col. 7, line 65 – col. 8, line 6). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Lang into the method of Martin in order to allow the user flexibility in setting up the apparatus correctly for any given procedure, and in order to allow for a more realistic simulation of the actual procedure.

Regarding claims 39 and 40, Martin discloses using a peripheral device that includes a catheter or other medical devices (5: 54-65). It is well known that a plunger is a useful medical device and thus a plunger is also anticipated by Martin (5: 54-65).

Response to Arguments

Applicant's arguments with respect to claims 21-25 and 30 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 17, 24-28, and 32-38 are allowed since the prior art does not teach of a ring being configured to rotate about a retainer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex Epshteyn whose telephone number is 571-272-5561. The examiner can normally be reached on M-F 8 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bob Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE



Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3714